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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,621	04/10/2001	Moshe Flashner-Barak	1662/52202	7987

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EXAMINER
PULLIAM, AMY E

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/829,621	Applicant(s) FLASHNER-BARAK, MOSHE	
	Examiner Amy E Pulliam	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,12-18,20-37,40-48 and 50-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,12-18,20-37,40-48 and 50-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Amendment A, and the Election, received by the Office on September 12, 2002.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9, 12-18, 20-37, 40-48, and 50-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/13914 to Hegedus *et al.* in view of US Patent 6,288,391 to Seo et al..

Hegedus *et al.* teach an invention related to water soluble products and pharmaceutical formulations in solid or liquid form (abstract). More specifically, Hegedus *et al.* teach that the composition comprises an active agent with a low aqueous solubility and a substantial binding affinity to plasma proteins. The reference teaches either human serum albumin or immunoglobulin as the plasma protein and paclitaxel as the active agent (p 41, claim 10). Hegedus *et al.* also teach that the formulation can be in solid or liquid form (p 43, claim 21). The reference describes the process of making, which includes dissolving the active in a solvent, combining the solution with a solution of the plasma protein, removing the organic solvent and lyophilizing the solution or its concentrate (p 44-45, claim 25).

Hegedus *et al.* never explicitly teach that the formulation be in the form of microspheres surrounded by a suspending solution. However, Hegedus does teach that the formulation can be in solid form.

Seo *et al.* teach a composition and method for treating diseases and disorders of the prostate. More specifically, Seo *et al.* teach a microsphere formulation comprising microspheres suspended in a liquid (c 3, l 43-45). The therapeutically effective substance will be combined with a biodegrable polymer to form the microspheres (c 3, l 25-26). The active agent can be an anticancer agent (c 3, l 20), such a paclitaxel (c 9, l 33). The biodegrable polymer is a member selected from the group consisting of polylactic acid, polyglycolic acid, or poly(lactic-co-glycolic) acid (c 3, l 32-36). The microspheres are generally between 1 and 100 microns, and the active agent comprises 10-50% of the total microsphere mass.

Neither reference specifically teaches the specific concentration limitations claimed by applicant. However, it is the position of the examiner that, absent a clear showing of criticality, the determination of these particular limitations is well within the skill of the ordinary worker as part of the process of normal optimization.

Although the reference does not specifically teach applicant's release rate, this is not considered a patentable distinction, absent comparative evidence. It is recommended that applicant provide comparative data showing any variance in release rates between the above combination and the instant application. Any such differences must be a result of limitations which are found in the instant claims. Otherwise, it is the position of the examiner that a particular release rate is a limitation which would be routinely determined by one of ordinary

skill in the art, through minimal experimentation, absent the showing of some unusual and/ or unexpected results.

Furthermore, it is the position of the examiner that one of ordinary skill in the art would have been motivated to combine the teachings of Hegedus and Seo. Hegedus teaches a solid or liquid formulation comprising paclitaxel and plasma proteins. Hegedus does not teach that the formulation be in the form of suspended microspheres. Seo teaches that PGA, PLA, and PGLA microspheres of paclitaxel are known in the art. One of ordinary skill in the art would look to the teachings of Seo in creating a solid or liquid formulation, as disclosed generally by Hegedus. The expected result would be a successful anti-cancer formulation.

Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

THURMAN K PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600